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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/472,232

12/27/1999

Jacques Dumas

BAYER-9-C1

8474

23599

7590

10/29/2002

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 10/29/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/472,232

Applicant(s)
Dumas et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 15, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 ☒ are pending in the application.
- 4a) Of the above, claim(s) 11-14 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-25 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on June 24, 2002.

Claims 1-25 are pending in this application.

Election/Restriction

Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9. Applicant's traversal that the restriction is improper is acknowledged, however, as explained in the previous office action, the search involved in burdensome. Applicant's argument that the search would not be burdensome because only one subclass has been identified for each group is fully considered but not deemed to be persuasive. A representative class/subclass was identified in the office action and it does not mean that the search is only limited to that one subclass. The invention of Group I is classified in class 548, several subclasses 356.1 to 379.7 and further several subclasses of classes 544 and 546 depending on the definitions of B, Ar, etc. It is once again emphasized that Groups I-III are drawn to structurally dissimilar compounds that are not art recognized equivalents. The restriction was made FINAL in the previous office action.

This application contains claims 1-8 and 15-25 (in part, i.e., compounds of formula I wherein A is thienyl or furyl) and 11-14 drawn to an invention nonelected with traverse in Paper

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No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The following rejections are withdrawn:

1. The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of applicant's amendments, except one which is maintained in this office action.
2. The rejection under 35 U.S.C. 102(e) over Regan et al., U.S. Patent No. 6,080,763 is withdrawn in view of the amendment. The claimed compounds require a substituent -Y-Ar on B. The reference does not disclose such compounds.
3. The rejection under 35 U.S.C. 103(a) over Regan et al., US'763 is hereby withdrawn in view of the amendments. The instant claims require a substituent -Y-Ar on B. The reference does not expressly teach compounds wherein R⁵ is a bridged aromatic group and therefore, does not provide any motivation to one of ordinary skill in the art to modify the reference compounds to prepare the instant compounds.
4. The rejection under 35 U.S.C. 103(a) over Creswell et al., U.S. Patent No. 5,162,360 is withdrawn in view of the amendments. The instantly amended compounds of formula I require a substituent -Y-Ar on B. As per the Genus-species guidelines of MPEP § 2144.08, the instantly claimed compounds are not deemed to be obvious over the reference compounds. The closest compound disclosed in the reference Example 23 and 24 differ from the instantly claimed

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compounds in at least two ways, and therefore, the reference is not deemed to provide motivation to one of ordinary skill in the art to prepare the instantly claimed compounds.

5. The rejection under 35 U.S.C. 112, first paragraph (page 9, paragraph 2 of the previous office action) is withdrawn in view of the amendments.

6. The rejection under 35 U.S.C. 103(a) over Regan et al., US'763 in view of Bruder et al. (J. Vir. 1997) is withdrawn in view of the applicant's remarks.

The following rejections are maintained:

1. Claims 15-23 are rejected under 35 U.S.C. 112, first paragraph for the reasons provided in the previous office action(s) which are incorporated herein by reference.

Applicant's cited decision, *Ex parte Henning* has been reviewed, however, is not deemed to be sufficient to overcome the instant rejection. In *Henning*, the compounds were disclosed to have 5-HT_{1A} antagonistic or serotonin inhibitory activities, which are well established in the art. Further, specification disclosed that 'the compounds have anxiolytic, antidepressant, antipsychotic, neuroleptic or antihypertensive activities' which was consistent with the claim language and thus, it was ruled that the evidence of record was sufficient to meet the enablement requirements. The instant claims on the other hand are drawn to "A method for the treatment of **disease** mediated by raf kinase...." (see claim 15) and the specification discloses that the compounds are useful 'in the treatment of tumors and/or cancerous cell growth mediated by raf kinase' (see page 2, lines 9-10). The background of the invention also provides discussion

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related to treatment of cancers. However, the recitation “**disease**” is understood for ‘an abnormal condition that impairs normal physiological functioning’ (as per Webster’s) and the instant claims include diseases other than cancers and there is nothing in the specification regarding what these diseases are. Further, the test procedures and data of the specification are drawn to the inhibition of oncogenic cell growth. There is nothing on the record to enable one skilled in the art to use the compounds in the treatment of all diseases mediated by raf kinase nor the does the record identify which diseases are contemplated. The dosage regimen at pages 16 of the specification is fully considered, however, the disclosure does not provide sufficient guidance or direction towards treatment of all ‘diseases’ mediated by raf kinase. As submitted by the applicant, “the particular method of administration will depend on a variety of factors” (see page 16, lines 31-32) and the instant application does not provide reasonable explanation of the ‘diseases mediated raf kinase’ within the scope of the claims and therefore, it will be undue burden on the skilled artisan to evaluate the diseases and further the variety of factors required to adopt the dosage regimen.

2. Claims 1-10, 17 and 24-25 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Particularly, the disclosure as filed does not support the definition of Ar as “5-10 membered aromatic structure” (appears in claims 1, 3, 17, etc.)

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Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the original claims describe Ar to be 5-10 membered aromatic structures', however, such description is not found to be present anywhere in the disclosure including the original claims. In fact, the original claim 1, page 37, line 12 clearly provides "Ar to be a 5- or 6-membered aromatic structure". The instant recitation is broader than the original definition provided for Ar and applicant has not provided where the instant recitation finds support in the disclosure as filed. Therefore, the rejection is maintained.

3. Claims 3 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reason provided in the previous office action which is incorporated here by reference. Particularly, the claims show two tricyclic moieties having a ring member NR^5 wherein the definition of R^5 is broader than the definition provided for X in the base claims on which claims 3 and 17 depend from, see e.g., the groups "up to per-halosubstituted C_6-C_{14} aryl and up to per-halo substituted C_3-C_{13} heteroaryl" recited in R^5 , are not supported by the definition of X.

Applicant's argues that the '3-ring formula is consistent with the scope of B and X as defined in claim 15', however, does not offer any explanation for claim 3 as compared to claim 1. It is again emphasized that while the tricyclic ring system is consistent with the definition of B, the groups "up to per-halosubstituted C_6-C_{14} aryl and up to per-halo substituted C_3-C_{13}

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heteroaryl” as a substituent on the tricyclic ring are not supported by X in claims 1 and 15 respectively because the definition of X does not provide ‘**substituted** C₆-C₁₄ aryl’ and ‘**substituted** C₃-C₁₃ heteroaryl’. Therefore, it is maintained that the dependent claims are broader than the base claims.

The following rejections are necessitated by the amendment:

Claims 1-10 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, the variable X is defined to be “substituted C₄-C₂₃ alkheteroaryl -Ar” (see page 2 of the amendment, last line). This recitation is not fully supported by the description in the specification or claims as originally filed. The original disclosure supports ‘substituted C₄-C₂₃ alkheteroaryl’, wherein the substituents are as provided in claim 1 (page 3, lines 1-4), however, the substituent list does not include Ar and therefore, the instantly recited group is not found to be supported by the original disclosure or claims.

The generic disclosure nor the examples provide any support for the above mentioned subject matter. Therefore, it is concluded that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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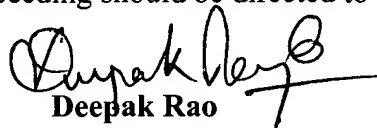
Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

October 25, 2002